UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION	)	MDL No. 2419 Dkt. No 1:13-md-2419 (RWZ)
THIS DOCUMENT RELATES TO: Suits Naming Specialty Surgery Center, PLLC	)	

SSC DEFENDANTS' RESPONSE TO PLAINTIFFS' STEERING COMMITTEE' LOCAL RULE 56.1 COUNTER-STATEMENT OF FACTS IN SUPPORT OF OPPOSITION TO SSC DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

Comes now the Defendants, Specialty Surgery Center, PLLC ("SSC"), Kenneth R. Lister, M.D. ("Dr. Lister), and Kenneth Lister, M.D., P.C. ("Dr. Lister's Practice") (collectively "SSC Defendants"), and respond to the Local Rule 56.1 Counter-Statement of Facts (Doc. 2998) filed by the Plaintiffs' Steering Committee ("PSC").

General Objections

Before responding to each purported statement of fact, the SSC Defendants object to the PSC's counter-statement in its entirety for failure to comply with Local Rule 56.1. Under Local Rule 56.1, statements of fact must be "concise." The PSC's counter-statement does not meet this baseline requirement. Not only does the PSC's counter-statement run nine (9) pages, but the vast majority of the purported "facts" are narrative and immaterial to the products liability issue, and should be stricken.[1]

Additionally, the purported "facts" are interspersed with argument and legal conclusions, and, as such, are inappropriate to include in a statement of facts. Moreover, it is readily apparent that most of the purported "facts" are not intended to assist the Court in making a legal determination on the dispositive legal issue, but instead are asserted only to (1) distract the Court from the legal arguments set forth in the SSC Defendants' motion and (2) attempt to convince the Court the SSC Defendants did something wrong and are somehow worthy of punishment. This is inappropriate and a waste of both the Court's and the parties' time.

[1] Fed. R. Civ. P. 12(f) ("The court may strike from a pleading…any redundant, **immaterial**, impertinent, or scandalous matter." (emphasis supplied))

Response to Counter-Statement of Undisputed Facts

Subject to the foregoing general objections, the SSC Defendants respond as follows:

1. To date, more than 750 people suffered fungal meningitis, fungal infections, or abscesses as a result of contaminated steroids originally compounded by the New England Company Center in Framingham, Massachusetts, and at least 64 people died. (Exhibit A to Declaration of Benjamin A. Gastel, *U. S. Centers for Disease Control and Prevention*).

RESPONSE: This paragraph is in no way material to the products liability issue before the Court at this time. Moreover, in support of this paragraph, the PSC cites to an update from the CDC's website. However, in its Responses to the SSC Defendants' First Requests for Admissions, the PSC refused to admit facts derived *from the same website*.[2] The PSC should not be allowed to pick and choose which portions of the CDC's website are reliable and which are not, depending on whether it wants to use the information offensively or the information hurts the PSC's position. In addition, in its Responses to the SSC Defendants' First Requests for Admissions, the PSC refused to admit the reliability and/or admissibility of several government publications (including those from the Department of Health Human Services ("DHHS"), CDC, and FDA).[3] The PSC should not now be allowed to rely on publications from those same entities in support of its opposition to the SSC Defendants' motion for summary judgment, again, using information when it helps

[2] *Compare* Doc. 2995-1, *with* PSC's Responses to SSC Defendants' First RFAs ¶¶ 133-140 (Excerpts attached as Ex. 1).
[3] *See* PSC's Responses to SSC Defendants' First RFAs ¶¶ 111-122; 133-140.

the PSC's position and refusing to admit its reliability when it hurts the PSC's position. As such, the Court should strike this paragraph.

Subject to the foregoing, the Court may deem this paragraph admitted for the limited purpose of deciding the motion for summary judgment.

2. Tainted steroids sickened 153 Tennesseans and killed 16 Tennesseans. (Exhibit A, *U. S. Centers for Disease Control and Prevention* [*sic*].

RESPONSE: This paragraph is in no way material to the products liability issue before the Court at this time. Moreover, in support of this paragraph, the PSC cites to an update from the CDC's website. However, in its Responses to the SSC Defendants' First Requests for Admissions, the PSC refused to admit facts derived *from the same website*.[4] The PSC should not be allowed to pick and choose which portions of the CDC's website are reliable and which are not, depending on whether it wants to use the information offensively or the information hurts the PSC's position. Additionally, in its Responses to the SSC Defendants' First Requests for Admissions, the PSC refused to admit the reliability and/or admissibility of several government publications (including those from DHHS, CDC, and FDA).[5] The PSC should not now be allowed to rely on publications from those same entities in support of its opposition to the SSC Defendants' motion for summary judgment, again, using information when it helps the PSC's position and refusing to admit its reliability when it hurts the PSC's position. As such, the Court should strike this paragraph.

[4] *Compare* Doc. 2995-1, *with* PSC's Responses to SSC Defendants' First RFAs ¶¶ 133-140.
[5] *See* PSC's Responses to SSC Defendants' First RFAs ¶¶ 111-122; 133-140.

Subject to the foregoing, the Court may deem this paragraph admitted for the limited purpose of deciding the motion for summary judgment.

3. According to the FDA, traditional compounding is the extemporaneous combining, mixing, or altering of ingredients by a pharmacist in response to a patient's prescription. (Ex. B, Depo. Exhibit No. 33; *see also* Exhibit C, Defendants' Responses to PSC's 1st Set of Requests for Admissions and Corresponding Interrogatory ("RFAs") with selected exhibits, Response to RFA No. 7 ("Response to RFA No. X")).

RESPONSE: This paragraph is in no way material to the products liability issue before the Court at this time. Moreover, in support of this paragraph, the PSC specifically relies on a 2006 survey by the FDA titled "2006 Limited FDA Survey of Compounded Drug Products." However, in its Responses to the SSC Defendants' First Requests for Admissions, the PSC refused to admit the reliability and admissibility of a similar governmental survey conducted by DHHS on compounding.[6] In its Supplemental Responses to the First Requests for Admissions, the PSC again denied the reliability of a similar governmental survey.[7] The PSC should not be allowed to pick and choose which governmental surveys on compounding are admissible and which are not, depending on whether they help or hurt the PSC's position. As such, the Court should strike this paragraph.

Subject to the foregoing, however, the Court may deem this paragraph admitted for the limited purpose of deciding the motion for summary judgment.

[6] *Compare* Doc. 2995-2, *with* PSC's Responses to SSC Defendants' First RFAs ¶¶ 111-122.
[7] *Compare* Doc. 2995-2, *with* PSC's Supplemental Responses to SSC Defendants' First RFAs ¶ 113 (Excerpts attached as Ex. 2).

4. Compounded drugs are mixed in response to a physician's prescription in order to create a medication tailored to the specialized needs of an individual patient. (Ex. B, Depo. Exhibit No. 33; *see* Exhibit C, Response to RFA No. 7).

RESPONSE: This paragraph is in no way material to the products liability issue before the Court at this time. Moreover, in support of this paragraph, the PSC specifically relies on a 2006 survey by the FDA titled "2006 Limited FDA Survey of Compounded Drug Products." However, in its Responses to the SSC Defendants' First Requests for Admissions, the PSC refused to admit the reliability and admissibility of a similar governmental survey conducted by DHHS on compounding.[8] Later, in its Supplemental Responses to the First Requests for Admissions, the PSC again denied the reliability of a similar governmental survey.[9] The PSC should not be allowed to pick and choose which governmental surveys on compounding are admissible and which are not, depending on whether they help or hurt the PSC's position. As such, the Court should strike this paragraph.

Subject to the foregoing, however, the Court may deem this paragraph admitted for the limited purpose of deciding the motion for summary judgment.

[8] *Compare* Doc. 2995-2, *with* PSC's Responses to SSC Defendants' First RFAs ¶¶ 111-122.
[9] *Compare* Doc. 2995-2, *with* PSC's Supplemental Responses to SSC Defendants' First RFAs ¶ 113.

5. Traditional compounding is used typically to prepare medications that are not available commercially, such as a drug for a patient who is allergic to an ingredient in a mass-produced product, or dilute dosages in children. (Exhibit D, Depo. Exhibit No. 32; Exhibit C, Response to RFA No. 12)

RESPONSE: This paragraph is in no way material to the products liability issue before the Court at this time. Moreover, in support of this paragraph, the PSC cites to a document published by the FDA. However, in its Responses to the SSC Defendants' First Requests for Admissions, the PSC refused to admit the reliability and/or admissibility of several government publications (including those from DHHS, CDC, and FDA).[10] The PSC should not be allowed to rely on publications from those same entities in support of its opposition to the SSC Defendants' motion for summary judgment after refusing to admit their reliability earlier. The parts that help a party's position cannot be reliable and the parts that hurt unreliable. As such, the Court should strike this paragraph.

Subject to the foregoing, the Court may deem this paragraph admitted for the limited purpose of deciding the motion for summary judgment.

[10] *Compare* Doc. 2995-4, *with* PSC's Responses to SSC Defendants' First RFAs ¶¶ 111-122; 133-140.

6. Because the law requires that compounding pharmacies compound specific medications in response to individual prescriptions, compounding pharmacies should not produce medications in bulk for mass distribution. (Exhibit D, Depo. Exhibit No. 32; and Ex. C, Response to RFA No. 12).

RESPONSE: This paragraph is in no way material to the products liability issue before the Court at this time. Moreover, in support of this paragraph, the PSC cites to a document published by the FDA. However, in its Responses to the SSC Defendants' First Requests for Admissions, the PSC refused to admit the reliability and/or admissibility of several government publications (including those from DHHS, CDC, and FDA).[11] The PSC should not now be allowed to rely on publications from those same entities in support of its opposition to the SSC Defendants' motion for summary judgment after refusing to admit their reliability earlier. The parts that help a party's position cannot be reliable and the parts that hurt unreliable. As such, the Court should strike this paragraph.

Subject to the foregoing, the Court may deem this paragraph admitted for the limited purpose of deciding the motion for summary judgment.

[11] *Compare* Doc. 2995-4, *with* PSC's Responses to SSC Defendants' First RFAs ¶¶ 111-122; 133-140.

7. Because compounding pharmacies were not supposed to produce medications in bulk for mass distribution, the FDA did not regulate them to the same degree as pharmaceutical companies. (*See* Exhibit D, Depo. Exhibit No. 32; Exhibit C, Response to RFA No. 12 (and Ex. 4 thereto)).

RESPONSE: This paragraph is in no way material to the products liability issue before the Court at this time. Moreover, in support of this paragraph, the PSC cites to a document published by the FDA. However, in its Responses to the SSC Defendants' First Requests for Admissions, the PSC refused to admit the reliability and/or admissibility of several government publications (including those from DHHS, CDC, and FDA).[12] The PSC should not now be allowed to rely on publications from those same entities in support of its opposition to the SSC Defendants' motion for summary judgment after refusing to admit their reliability earlier. The parts that help a party's position cannot be reliable and the parts that hurt unreliable. As such, the Court should strike this paragraph.

Subject to the foregoing, the Court may deem this paragraph admitted for the limited purpose of deciding the motion for summary judgment.

[12] *Compare* Doc. 2995-4, *with* PSC's Responses to SSC Defendants' First RFAs ¶¶ 111-122; 133-140.

8. The FDA generally leaves regulation of compounding pharmacies to state pharmacy boards (*See* Exhibit D, Exhibit No. 32, Response to RFA No. 12).

RESPONSE: This paragraph is in no way material to the products liability issue before the Court at this time. Moreover, in support of this paragraph, the PSC cites to a document published by the FDA. However, in its Responses to the SSC Defendants' First Requests for Admissions, the PSC refused to admit the reliability and/or admissibility of several government publications (including those from DHHS, CDC, and FDA).[13] The PSC should not now be allowed to rely on publications from those same entities in support of its opposition to the SSC Defendants' motion for summary judgment after refusing to admit their reliability earlier. The parts that help a party's position cannot be reliable and the parts that hurt unreliable. As such, the Court should strike this paragraph.

Subject to the foregoing, the Court may deem this paragraph admitted for the limited purpose of deciding the motion for summary judgment.

[13] *Compare* Doc. 2995-4, *with* PSC's Responses to SSC Defendants' First RFAs ¶¶ 111-122; 133-140.

9. In 2002 (ten years before the meningitis catastrophe), the CDC published a report regarding at least two cases of fungal meningitis arising from contaminated medication used in epidural injections. That report concluded: "purchasers of pharmaceuticals should determine if supplies are provided from a compounding pharmacy that . . . follows appropriate measures to ensure that injectable products are free of contamination. (*See* Exhibit E, Depo. Ex. No. 35; Ex. C, Response to RFA No. 1).

RESPONSE: This paragraph is in no way material to the products liability issue before the Court at this time. Moreover, in support of this paragraph, the PSC cites to a document published by the CDC. However, in its Responses to the SSC Defendants' First Requests for Admissions, the PSC refused to admit the reliability and/or admissibility of several government publications (including those from DHHS, CDC, and FDA).[14] The PSC should not now be allowed to rely on publications from those same entities in support of its opposition to the SSC Defendants' motion for summary judgment after refusing to admit their reliability earlier. The parts that help a party's position cannot be reliable and the parts that hurt unreliable. As such, the Court should strike this paragraph.

Subject to the foregoing, the Court may deem this paragraph admitted for the limited purpose of deciding the motion for summary judgment.

[14] *Compare* Doc. 2995-5, *with* PSC's Responses to SSC Defendants' First RFAs ¶¶ 111-122; 133-140.

10. On March 24, 2005 (seven years before the meningitis catastrophe), *USA Today* published a front page article with the following headline: "*Safety concerns grow over pharmacy-mixed drugs*." That article discussed growing concern over the fact that drugs produced in bulk by compounding pharmacies are not FDA approved and are not subject to the same oversight as drugs produced by pharmaceutical companies. (*See* Exhibit F; and Exhibit C, Response to RFA No. 6).

RESPONSE: This paragraph is in no way material to the products liability issue before the Court at this time. In addition, it cites to a USA Today news article dated March 24, 2005. This is inadmissible hearsay evidence, and the Court should not consider it.

Subject to the foregoing, the Court may deem this paragraph admitted for the limited purpose of deciding the motion for summary judgment.

11. In 2006 (six years before the catastrophe), the FDA conducted a survey of compounded drug products. They collected 36 samples from compounding pharmacies across the United States during unannounced visits. Twelve of the 36 samples (33%) failed analytical testing. The FDA survey concluded "*poor quality compounded drugs are a serious public health concern, as improperly compounded products have been linked to grave adverse events, including deaths*." (*See* Exhibit B, Depo. Ex. No. 33; and Ex. C, Response to RFA No. 7).

RESPONSE: This paragraph is in no way material to the products liability issue before the Court at this time. Moreover, in support of this paragraph, the PSC specifically relies on a 2006 survey by the FDA titled "2006 Limited FDA Survey of Compounded Drug Products." However, in its Responses to the SSC Defendants' First Requests for Admissions, the PSC refused to admit the reliability and admissibility of a similar governmental survey conducted by DHHS on compounding.[15] Later, in its Supplemental Responses to the First Requests for Admissions, the PSC again denied the reliability of a similar governmental survey.[16] The PSC should not be allowed to pick and choose which governmental surveys on compounding are admissible and which are not, depending on whether they help or hurt the PSC's position. As such, the Court should strike this paragraph.

Subject to the foregoing, however, the Court may deem this paragraph admitted for the limited purpose of deciding the motion for summary judgment.

[15] *Compare* Doc. 2995-2, *with* PSC's Responses to SSC Defendants' First RFAs ¶¶ 111-122.
[16] *Compare* Doc. 2995-2, *with* PSC's Responses to SSC Defendants' First RFAs ¶ 113.

12. In May 2007 (five years before the catastrophe), the FDA published an article titled: "*The Special Risks of Pharmacy Compounding*." That article highlighted numerous adverse events involving compounded products. It also warned of the emergence of large scale compounding operations that were clearly operating outside the bounds of traditional compounding practice." (*See* Exhibit D, Depo. Ex. No. 32; and Exhibit C, Response to RFA No. 7 (and Ex. 4 thereto).)

RESPONSE: This paragraph is in no way material to the products liability issue before the Court at this time. Moreover, in support of this paragraph, the PSC cites to a document published by the FDA. However, in its responses to the SSC Defendants' First Request for Admissions, the PSC refused to admit the reliability and/or admissibility of several government publications (including those from DHHS, CDC, and FDA).[17] The PSC should not now be allowed to rely on publications from those same entities in support of its opposition to the SSC Defendants' motion for summary judgment after refusing to admit their reliability earlier. The parts that help a party's position cannot be reliable and the parts that hurt unreliable. As such, the Court should strike this paragraph.

Subject to the foregoing, the Court may deem this paragraph admitted for the limited purpose of deciding the motion for summary judgment.

[17] *Compare* Doc. 2995-4, *with* PSC's Responses to SSC Defendants' First RFAs ¶¶ 111-122; 133-140.

13. In 2010 (two years before the catastrophe), the FDA posted an educational video on YouTube regarding concerns over the quality of compounded drugs. (*See* Exhibit C, Response to RFA No. 17.)

RESPONSE: This paragraph is in no way material to the products liability issue before the Court at this time. In addition, it cites to a YouTube video. This is inadmissible hearsay, and the Court should not consider it.

Subject to the foregoing, the Court may deem this paragraph admitted for the limited purpose of deciding the motion for summary judgment.

14. On November 5, 2010 (about two years before the catastrophe), the American Society of Anesthesiologists, the American Society of Health-System Pharmacists ("ASHP") and other medical societies published a joint report regarding drug shortages. That report included an article written by the ASHP stating as follows:

> Compounding pharmacies have also pursued the production of drugs that are in short supply. Caution is warranted because preparations from these pharmacies may not meet applicable state or federal standards (e.g., United States Pharmacopeia chapter 797 or FDA labeling requirements). The sources of raw materials used by compounding pharmacies have been questioned, and apparent lapses in quality control have resulted in serious patient injury, including death.
> . . .
> Compounding pharmacies may also present patient risks; several deaths have been associated with improperly sterilized compounded products.

(*See* Exhibit G (joint report); Exhibit C, Response to RFA No. 18.)

RESPONSE: This paragraph is in no way material to the products liability issue before the Court at this time. In addition, it cites to a report by the American Society of Health-System Pharmacists. This is inadmissible hearsay, and the Court should not consider it.

Subject to the foregoing, the Court may deem this paragraph admitted for the limited purpose of deciding the motion for summary judgment.

15. In May 2012 (a few months before the meningitis catastrophe), the CDC published a report regarding fungal infections arising from medications obtained from a compounding pharmacy. That report advised that "contamination of compounded sterile preparations has caused outbreaks. Since 1990, FDA has learned of approximately 200 adverse events associated with 71 compounded products." (Exhibit H (report); Exhibit C, Response to RFA No. 19.)

RESPONSE: This paragraph is in no way material to the products liability issue before the Court at this time. Moreover, in support of this paragraph, the PSC cites to a document published by the CDC. However, in its responses to the SSC Defendants' First Request for Admissions, the PSC refused to admit the reliability and/or admissibility of several government publications (including those from DHHS, CDC, and FDA).[18] The PSC should not now be allowed to rely on publications from those same entities in support of its opposition to the SSC Defendants' motion for summary judgment after refusing to admit their reliability earlier. The parts that help a party's position cannot be reliable and the parts that hurt unreliable. As such, the Court should strike this paragraph.

Subject to the foregoing, the Court may deem this paragraph admitted for the limited purpose of deciding the motion for summary judgment.

[18] *Compare* Doc. 2995-8, *with* PSC's Responses to SSC Defendants' First RFAs ¶¶ 111-122; 133-140.

16. NECC was the subject of multiple complaints to and investigations by the FDA and the Massachusetts Board of Registration in Pharmacy that often focused on unsterile conditions at NECC's facilities. (*See* Exhibit I; The Committee on Energy and Commerce Majority Memorandum Re: Hearing on "The Fungal Meningitis Outbreak: Could It Have Been Prevented?", pp. 6 – 25).)

RESPONSE: This paragraph is in no way material to the products liability issue before the Court at this time. As such, the Court should strike this paragraph.

Subject to the foregoing, however, the Court may deem this paragraph admitted for the limited purpose of deciding the motion for summary judgment.

17. In 2006, the FDA issued a warning letter to NECC, detailing numerous problems at NECC including the sale of compounded drugs without patient-specific prescriptions, the compounding of commercially available drugs, the selling of misbranded drugs, and problems with storage and sterility. (*See* Exhibit J, Depo. Exhibit No. 306.)

RESPONSE: This paragraph is in no way material to the products liability issue before the Court at this time. As such, the Court should strike this paragraph.

Subject to the foregoing, however, the Court may deem this paragraph admitted for the limited purpose of deciding the motion for summary judgment.

18. The Defendants operated a high volume pain clinic that distributed hundreds of vials of Depo-Medrol to patients each year. (Exhibit K, Depo. Exhibit No. 99, **Filed Under Seal**; Exhibit L, Depo. Exhibit No. 100, **Filed Under Seal**; Exhibit M, Excerpts of Jean Atkinson Deposition ("Atkinson Dep.") at 29-30; 46-53; Exhibit N, Excerpt of Deposition of Jeffrey Ebel ("Ebel Dep.") at 14; Exhibit O, Excerpts of Deposition of Dr. Kenneth Lister ("Lister Dep.") at 133-34.)

RESPONSE: This paragraph is in no way material to the products liability issue before the Court at this time. Plus, the fairly obvious suggestion in the paragraph – that the "volume" of Dr. Lister's practice in Crossville, Tennessee, was somehow unsafe and profit-driven – has nothing to do with the legal issues before the Court. As such, the Court should strike this paragraph.

Subject to the foregoing, however, the Court may deem this paragraph admitted for the limited purpose of deciding the motion for summary judgment.

19. In 2012, Dr. Kenneth Lister, a part owner of SSC, performed as many as 14 epidural steroid injections per day at SSC. (Exhibit O, Lister Dep. at 204.)

RESPONSE: This paragraph is in no way material to the products liability issue before the Court at this time. Plus, the fairly obvious suggestion – that Dr. Lister did so many injections each day that he could not guarantee their safety – has nothing to do with the legal issues before the Court. As such, the Court should strike this paragraph.

Subject to the foregoing, however, the Court may deem this paragraph admitted for the limited purpose of deciding the motion for summary judgment.

20. In 2012, Jean Atkinson was the Director of Nursing for SSC. (Exhibit M, Atkinson Dep. at 78:5-6.)

RESPONSE: This paragraph is in no way material to the products liability issue before the Court at this time. As such, the Court should strike this paragraph.

Subject to the foregoing, however, the Court may deem this paragraph admitted for the limited purpose of deciding the motion for summary judgment.

21. In 2012, defendant Calisher & Associates performed management services for SSC. (Exhibit P, Excerpts of Deposition of Gina Calisher as 30(b)(6) Representative for Calisher & Associates ("Calisher Dep."), at 18-19.)

RESPONSE: This paragraph is in no way material to the products liability issue before the Court at this time. As such, the Court should strike this paragraph.

Subject to the foregoing, however, the Court may deem this paragraph admitted for the limited purpose of deciding the motion for summary judgment.

22. In July 2012, SSC switched to purchasing compounded MPA from NECC, and SSC, Dr. Lister, and Calishers all participated in that decision. (Exhibit M, Atkinson Dep. at 38-39, 78:14-19; 94:5-95:1; 107-108; Exhibit O, Lister Dep. 128; 136; 190-91).

RESPONSE: This paragraph is in no way material to the products liability issue before the Court at this time. As such, the Court should strike this paragraph.

Subject to the foregoing, however, the Court may deem this paragraph admitted for the limited purpose of deciding the motion for summary judgment.

23. When SSC switched to purchasing compounded MPA from NECC in July 2012, SSC, Dr. Lister, nor Calishers did any of the following:

a. Investigate whether NECC had any regulatory actions against them because of previous problems;

b. Investigate NECC had a history of producing contaminated products;

c. Investigate whether anyone state or federal agencies had made any complaints or taken any actions against NECC;

d. Contact the Tennessee Department of Health about NECC;

e. Contact any state board of pharmacy about NECC;

f. Consult with experts or attorneys concerning regulatory compliance issues, the safety of compounding pharmacies, and the legality of purchasing from them in bulk;

g. Research the differences between compounded pharmacies and FDA-licensed distributors;

h. Conduct a Google search of NECC;

i. No attempt to visit NECC's facilities;

j. No review of FDA publications and warnings, media articles, or medical literature regarding the dangers of compounded drugs.

k. No research concerning the safety and risks of compounded medications;

l. No effort to verify information contained in NECC promotional literature.

(*See* Exhibit M, Atkinson Dep. at 41, 64-68, 76); Exhibit O, Lister Dep. at 136-38; Exhibit P, Calisher Dep. at 27, 32-33, 90-92)

RESPONSE: This paragraph is in no way material to the products liability issue before the Court at this time. It is a thinly-veiled attempt to make an opening statement in a response to a statement of facts for a legal motion. As such, the Court should strike this paragraph.

Subject to the foregoing, however, the Court may deem this paragraph admitted for the limited purpose of deciding the motion for summary judgment.

24. In 2012, SSC did not subscribe to any medical journals. (Exhibit O, Lister at 56:5-7.)

RESPONSE: This paragraph is in no way material to the products liability issue before the Court at this time. It is probably not even relevant to any issue in the case, much less this legal issue. As such, the Court should strike this paragraph.

Subject to the foregoing, however, the Court may deem this paragraph admitted for the limited purpose of deciding the motion for summary judgment.

25. Prior to July 2012, SSC purchased Depo-Medrol from Besse Medical and CuraScript, both of which sold only FDA-approved pharmaceuticals. (Exhibit K, Depo. Exhibit No. 99, **Filed Under Seal**; Exhibit L, Depo. Exhibit No. 100, **Filed Under Seal**; Exhibit M, Atkinson Dep. at 29-30; 46-53; Exhibit N, Ebel Dep. at 14; Exhibit O, Lister Dep. at 133-34).

RESPONSE: This paragraph is in no way material to the products liability issue before the Court at this time. As such, the Court should strike this paragraph.

Subject to the foregoing, however, the Court may deem this paragraph admitted for the limited purpose of deciding the motion for summary judgment.

26. Prior to July 2012, SSC had never purchased steroids for use in epidural steroid injections from compounding pharmacies. (Exhibit O, Lister Dep. at 133-134.)

RESPONSE: This paragraph is in no way material to the products liability issue before the Court at this time. As such, the Court should strike this paragraph.

Subject to the foregoing, however, the Court may deem this paragraph admitted for the limited purpose of deciding the motion for summary judgment.

27. In July 2012, SSC chose to stop purchasing FDA-approved steroids through Besse Medical and CuraScript, and started purchasing compounded MPA in bulk from NECC. (Exhibit M, Atkinson Dep. at 58.)

RESPONSE: This paragraph is in no way material to the products liability issue before the Court at this time. As such, the Court should strike this paragraph.

Subject to the foregoing, however, the Court may deem this paragraph admitted for the limited purpose of deciding the motion for summary judgment.

28. Prior to the September 2012 fungal meningitis outbreak, SSC was always able to obtain Depo-Medrol for its patients, and never had to cancel a patient's scheduled procedure because Depo-Medrol was unavailable. (Exhibit O, Lister Dep. at 132; Exhibit M, Atkinson Dep. at 45)

RESPONSE: This paragraph is in no way material to the products liability issue before the Court at this time. As such, the Court should strike this paragraph.

Subject to the foregoing, however, the Court may deem this paragraph admitted for the limited purpose of deciding the motion for summary judgment.

29. Prior to SSC's switch to purchasing compounded MPA from NECC, Calishers did not contact any pharmaceutical wholesalers to determine whether a sufficient supply of Depo-Medrol in fact was unavailable. (Exhibit P, Calishers Dep. at 33.)

RESPONSE: This paragraph is in no way material to the products liability issue before the Court at this time. As such, the Court should strike this paragraph.

Subject to the foregoing, however, the Court may deem this paragraph admitted for the limited purpose of deciding the motion for summary judgment.

30. According to internal SSC records, SSC purchased from NECC because it offered a "good price" for its compounded MPA. (Exhibit Q, SSC-07622-23, **Filed Under Seal**).

RESPONSE: This paragraph is in no way material to the products liability issue before the Court at this time. It is also a significant misstatement of the facts and testimony in the case. As such, the Court should strike this paragraph.

Subject to the foregoing, however, the Court may deem this paragraph admitted for the limited purpose of deciding the motion for summary judgment.

31. According to invoices produced by SSC, the clinic purchased hundreds of vials of MPA from NECC between July 2012 and September 2012. (Collective Exhibit R, Depo. Exhibit Nos. 93 and 94.)

RESPONSE: This paragraph is in no way material to the products liability issue before the Court at this time. As such, the Court should strike this paragraph.

Subject to the foregoing, however, the Court may deem this paragraph admitted for the limited purpose of deciding the motion for summary judgment.

32. SSC made its bulk purchases of MPA from NECC without filling out a valid patient-specific prescription for each patient who received an injection of NECC-compounded MPA. (Exhibit M, Atkinson Dep. at 104-106; 113; Exhibit O, Lister Dep. at 199).

RESPONSE: This paragraph is in no way material to the products liability issue before the Court at this time. As such, the Court should strike this paragraph.

Subject to the foregoing, however, the Court may deem this paragraph admitted for the limited purpose of deciding the motion for summary judgment.

33. The Defendants operated a for-profit corporation. (Exhibit S, Excerpts from Kimberly Bowlin Deposition ("Bowlin Dep.") at 26:17-10.)

RESPONSE: This paragraph is in no way material to the products liability issue before the Court at this time. As such, the Court should strike this paragraph.

Subject to the foregoing, however, the Court may deem this paragraph admitted for the limited purpose of deciding the motion for summary judgment.

34. When the Defendants performed an epidural steroid injection, they expected to be paid for each injection. (Exhibit S, Bowlin Dep. at 26:21-25.)

RESPONSE: In response to this paragraph, the SSC Defendants would first point out to the Court that the transcript cited in support of this paragraph does not say what the PSC indicates it does. Rather, at page 26, lines 21-25, Kim Bowlin testified as follows:

> **Q. So if a – if a patient received an endoscopy at Specialty Surgery Center, Specialty Surgery Center would expect to be paid, correct?**
> **A. Yes. Either from the patient or their insurance carrier.[19]**

[19] *See* Doc. 2995-19 at 3.

An endoscopy is not an epidural steroid injection. For this reason alone, the Court should strike this paragraph. This paragraph should also be stricken because it is in no way material to the products liability issue before the Court at this time.

Subject to the foregoing, it is undisputed that the SSC Defendants expected to be paid for the services they provided to the Plaintiffs.

35. In the Summer of 2012, Dr. Lister was the only doctor at the Special Surgery Center who performed epidural steroid injections. (Exhibit S, Bowlin Dep. at 27:22-25.)

RESPONSE: Undisputed for purposes of summary judgment only.

36. The Defendants provided epidural steroids to patients in exchange for money. (Exhibit S, Bowlin Dep. 27:14-17.)

RESPONSE: This paragraph is in no way material to the products liability issue before the Court at this time.

Subject to the foregoing, it is undisputed the that Kim Bowlin testified as follows:

> **Q. And Specialty Surgery Center provided epidural steroids to patients in exchange for money, correct?**
> **A. Yes.[20]**

However, the SSC Defendants also affirmatively note that Dr. Lister testified as follows:

> **Q. Well, let's break those out. Did Specialty Surgery Center charge for the procedure in 2012 for epidural steroid injections?**
> **A. Yes, Specialty Surgery Center did charge for the procedure.**
> **Q. And what do you mean when you say the procedure?**
> **A. The charge was an all-inclusive charge for the procedure of performing the epidural steroid injections.**
> **Q. And that charge included the charge for the steroid itself?**
> **A. I presume the charge for the steroid itself was included in the overall charge for the procedure.**

[20] *See* Doc. 2995-19 at 4.

Q. And so what did you charge for?
A. I charged simply for my services of administering the epidural steroid injection.
Q. And Specialty Surgery charged for everything other than your services?
A. Correct.
Q. Part of the money that was paid to Specialty Surgery Center in 2012 for the epidural steroid itself; is that right?
A. The money was a global payment from the insurance company.
Q. Was the steroid free?
A. The steroid was a cost to the surgery center, but the money was a global payment for the epidural steroid.

****

A. Specialty Surgery Center provided and billed for those services for the epidural steroid injections.
Q. And that included the epidural steroid itself?
A. They billed for the full service.[21]

37. Dr. Lister received payment for each epidural steroid injection that he performed, separate and apart from money that was paid to SSC for each injection. (Exhibit O, Lister Dep. at 28-29)

RESPONSE: It is undisputed that Dr. Lister and SSC were paid in connection with the epidural steroid injection procedures. Dr. Lister "charged simply for [his] services of administering the epidural steroid injection,"[22] **and SSC charged "an all-inclusive charge for the procedure of performing the epidural steroid injections."**[23]

38. In 2012, Dr. Lister performed approximately 40 to 60 epidural steroid injections per month. (Exhibit O, Lister Dep. at 104.)

RESPONSE: Undisputed for purposes of summary judgment only.

[21] *See* Doc. 2995-15 at 5-6, 8.
[22] *See* Doc. 2995-15 at 5.
[23] *See* Doc. 2995-15 at 5.

39. Dr. Lister's pain management services, about half of which constituted epidural steroid injections, represented approximately one-third of SSC's procedure volume between January 2012 and September 2012. (Exhibit O, Lister Dep. at 103)

RESPONSE: Undisputed for purposes of summary judgment only.

40. When SSC administered epidural steroid injections to patients, SSC charged patients for the injection separately from the services of Dr. Lister, the physician who injected the medicine. (Exhibit O, Lister Dep. at 34-35; 65; 121)

RESPONSE: It is undisputed Dr. Lister charged for his services of administering the epidural steroid injection and SSC charged an all-inclusive charge for the procedure of performing the epidural steroid injections.[24]

41. With respect to SSC's charges associated with each epidural steroid injection, SSC charged patients a fee that included charges for the steroid itself. (Exhibit O, Lister Dep. at 34; 65-66)

RESPONSE: It is undisputed that Dr. Kenneth Lister testified as follows:

Q. Well, let's break those out. Did Specialty Surgery Center charge for the procedure in 2012 for epidural steroid injections?
A. Yes, Specialty Surgery Center did charge for the procedure.
Q. And what do you mean when you say the procedure?
A. The charge was an all-inclusive charge for the procedure of performing the epidural steroid injections.
Q. And that charge included the charge for the steroid itself?
A. I presume the charge for the steroid itself was included in the overall charge for the procedure.

****

Q. Part of the money that was paid to Specialty Surgery Center in 2012 for the epidural steroid itself; is that right?
A. The money was a global payment from the insurance company.
Q. Was the steroid free?
A. The steroid was a cost to the surgery center, but the money was a global payment for the epidural steroid.

****

[24] *See* Doc. 2995-15 at 5.

A. Specialty Surgery Center provided and billed for those services for the epidural steroid injections.
Q. And that included the epidural steroid itself?
A. They billed for the full service.[25]

42. SSC received the same reimbursement from insurance companies for epidural steroid injections regardless of how much SSC paid for the underlying steroid. (Exhibit O, Lister Dep. at 122-123)

RESPONSE: It is undisputed that Dr. Kenneth Lister testified as follows:

Q. Do you know whether the reimbursement to Specialty Surgery Center for epidural steroid injections changed depending on how much Specialty Surgery Center paid for the steroid itself?
A. No.
Q. No, you don't know or, no, it didn't change?
A. It didn't change.
Q. Okay. So however much Specialty Surgery Center paid for the steroid itself, the reimbursement from the insurance companies was always the same?
A. Correct.[26]

43. If SSC paid less for a steroid product, it would have retained more of the reimbursement amount associated with an epidural steroid injection. (Exhibit O, Lister Dep. at 123)

RESPONSE: It is undisputed that Dr. Kenneth Lister testified as follows:

Q. So if the amount that Specialty Surgery Center paid for a steroid product were less, then Specialty Surgery Center would be able to put more of the reimbursement to its bottom line?
A. I guess that's an assumption, yes.
Q. Is that an accurate assumption?
A. It would seem reasonable.[27]

[25] *See* Doc. 2995-15 at 5-6, 8.
[26] *See* Doc. 2995-15 at 12-13.
[27] *See* Doc. 2995-15 at 12-13.

44. After SSC began purchasing MPA from NECC with Dr. Lister's knowledge, Dr. Lister did not inform any of his patients injected with that MPA that it had been purchased from a compounding pharmacy. (Exhibit O, Lister 127)

RESPONSE: This paragraph is in no way material to the products liability issue before the Court at this time. As such, the Court should strike this paragraph.

Subject to the foregoing, however, the Court may deem this paragraph admitted for the limited purpose of deciding the motion for summary judgment.

45. Dr. Lister did not tell of the patients into whom he injected NECC MPA that the product did not contain preservatives. (Exhibit O, Lister Dep. at 127)

RESPONSE: This paragraph is in no way material to the products liability issue before the Court at this time. As such, the Court should strike this paragraph.

Subject to the foregoing, however, the Court may deem this paragraph admitted for the limited purpose of deciding the motion for summary judgment.

Respectfully submitted,

GIDEON, COOPER & ESSARY, PLC

/s/ Chris J. Tardio
C.J. Gideon, Jr.*
Chris J. Tardio*
Alan S. Bean**
Matthew H. Cline*
315 Deaderick Street, Suite 1100
Nashville, TN 37238
(615) 254-0400 (Phone
(615) 254-0459 (Fax)
chris@gideoncooper.com

Attorneys for the SSC Defendants

/s/ Kent E. Krause
PARKS T. CHASTAIN**
KENT E. KRAUSE**
ASHLEY E. GENO**
Attorneys for Defendant, Specialty Surgery Center, PLLC

BREWER, KRAUSE, BROOKS & CHASTAIN, PLLC
P. O. Box 23890
Nashville, TN 37202-3890
(615) 256-8787 (PTC)
(615) 256-8985 (Fax)
pchastain@bkblaw.com
kkrause@bkblaw.com
ageno@bkblaw.com

*Admitted pursuant to MDL Order No. 1
**Admitted pro hac vice

CERTIFICATE OF SERVICE

I hereby certify that this document filed through the CM/ECF system will be served electronically to the registered participants identified on the Notice of Electronic Filing and copies will be served via electronic mail or regular U.S. mail to those participants identified as unregistered this the 3rd day of August, 2016.

/s/ Chris J. Tardio
CHRIS J. TARDIO